



Institutional Review Board Human Research Northern Kentucky University

Institutional Review Board (IRB)

IRBs are federally required to review and approve human participant research before it is initiated. Research is a systematic investigation, including development, testing, and evaluation designed to develop or contribute to generalized knowledge. If your intent is to contribute to general knowledge, rather than strictly to benefit the participants, your activities constitute research, and must be reviewed.

The IRB seeks to ensure that:

- Any risks that participants may incur are proportional to expected benefits
- The rights, welfare, and privacy of human participants and their data are maintained
- Informed consent documents clearly describe risks and the true nature of research
- Participants voluntarily participate and are free to withdraw without penalty

IRB Process:

1. Complete CITI training found at www.citiprogram.org with an 80% passing grade on each of six modules, required of all researchers, faculty advisors, and IRB committee members.
2. Complete IRB application found at <http://rgc.nku.edu/forms.html#irb>, attach CITI training completion certificate showing modules completed, and submit to IRB Administrator.
3. Following review, the IRB may:
 - a. Approve as Exempt from ongoing oversight – proposed study involves no more than minimal risk to participants and falls into one of six narrowly defined categories (see <http://rgc.nku.edu/forms.html#irb>).
 - b. Approve as Expedited with ongoing oversight – proposed study involves no more than minimal risk. Minimal risk refers to activities for which the extent of harm or expected discomfort are not greater than those encountered in daily life of a normal, healthy person. Risk includes inadvertent release of or unauthorized access to data.
 - c. Approve with Full Board Review – proposed study may involve greater than minimal risk and/or research with vulnerable populations (e.g., minors, those with legal impingements on their freedom, or the decisionally impaired).
 - d. Not approve following Full Board Review
 - e. **All studies involving human participants or collecting human data should be submitted for IRB review.**
4. Approval is for one year, unless modifications are made to the study protocol. The Principal Investigator is responsible for submitting a revised IRB application if the approved research protocol is changed, or a continued IRB application prior to expiration date.
5. Note: If a researcher intends to contribute to general knowledge or receive academic credit for conducting a study, IRB review is needed.

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